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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,059	09/23/2003	Victor Schoenle	10527-477001	2738

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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
AUGHENBAUGH, WALTER	
ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
12/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,059	SCHOENLE ET AL.	
	Examiner	Art Unit	
	WALTER B. AUGHENBAUGH	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74,77-84,87-91,130-133 and 140-153* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74, 77-84, 87-91, 130-133 and 140-153* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 11, 2008 has been entered.

WITHDRAWN REJECTIONS

2. All rejections of the claims under 35 U.S.C. 102 and 103 made of record in the previous Office Action mailed June 9, 2008 have been withdrawn due to Applicant's amendments in claims 74, 80, 84 and 89 in the Amendment filed September 11, 2008.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 149 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how "the region" can be "attached to a proximal waist of the balloon" as is recited in claim 149 if claim 74 requires that "a length of the catheter shaft extending between the proximal end of the catheter shaft and the proximal end of the balloon has no balloons attached thereto". Clarification is requested.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 74, 77-84, 87-91, 130-133 and 140-153 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulkerson et al. (USPN 6,344,044) as evidenced by Berg et al. (USPN 5,674,208).

In regard to independent claims 74 and 80, Fulkerson et al. teach a balloon catheter that corresponds to the balloon catheter as claimed. Fulkerson et al. teach that the shaft includes a region that comprises a polyamide having a tensile strength of greater than 21,000 psi because Fulkerson et al. teach that the shaft comprises Kevlar™ fiber (col. 4, lines 48-64), which has a tensile strength of up to 400 Kpsi (400,000 psi) as evidenced by Berg et al. (USPN 5,674,208, see col. 1, lines 55-62). Kevlar™ is an aramid, which is a polyamide.

Fulkerson et al. fail to explicitly teach the thickness of the wall of the shaft.

However, Fulkerson et al. teach that while the wall should be strong enough to withstand the expansion force of the stent, it should also be flexible enough to allow for intravascular maneuvering (col. 4, lines 48-64). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the thickness of the wall of the shaft of Fulkerson et al. in order to achieve the desired degree of flexibility of the wall in order to allow for intravascular maneuvering depending on the particular desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claims 77 and 81, since the Kevlar is embedded in a polymeric material (col. 4, lines 48-64), the Kevlar corresponds to a layer and the polymeric material forms two separate different layers (i.e. the polymeric material that surrounds [above and below the Kevlar layer] the Kevlar), and these layers have different flexibilities because they comprise different materials.

In regard to claims 78 and 82, Fulkerson et al. teach that the shaft includes a region that comprises a polyamide having a tensile strength of greater than 22,500 psi because Fulkerson et al. teach that the shaft comprises Kevlar™ fiber (col. 4, lines 48-64), which has a tensile strength of up to 400 Kpsi (400,000 psi) as evidenced by Berg et al. (USPN 5,674,208, see col. 1, lines 55-62).

In regard to claims 79 and 83, Fulkerson et al. teach that the shaft includes a region that comprises a polyamide having a hoop stress of greater than 3300 psi because Fulkerson et al. teach that the shaft comprises Kevlar™ fiber (col. 4, lines 48-64), which has a tensile strength of up to 400 Kpsi (400,000 psi) as evidenced by Berg et al. (USPN 5,674,208, see col. 1, lines 55-62). Since the tensile strength of Kevlar™ approaches 20 times greater than Applicant's claimed minimum tensile strength, the hoop stress (hoop strength) of Kevlar™ is also significantly greater than Applicant's claimed minimum hoop stress.

In regard to independent claims 84 and 89, Fulkerson et al. teach a balloon catheter that corresponds to the balloon catheter as claimed. Fulkerson et al. teach that the shaft includes a region that comprises a polyamide having a hoop stress of greater than 3300 psi because Fulkerson et al. teach that the shaft comprises Kevlar™ fiber (col. 4, lines 48-64), which has a tensile strength of up to 400 Kpsi (400,000 psi) as evidenced by Berg et al. (USPN 5,674,208,

see col. 1, lines 55-62). Since the tensile strength of Kevlar™ approaches 20 times greater than Applicant's claimed minimum tensile strength, the hoop stress (hoop strength) of Kevlar™ is also significantly greater than Applicant's claimed minimum hoop stress. Kevlar™ is an aramid, which is a polyamide.

Fulkerson et al. fail to explicitly teach the thickness of the wall of the shaft.

However, Fulkerson et al. teach that while the wall should be strong enough to withstand the expansion force of the stent, it should also be flexible enough to allow for intravascular maneuvering (col. 4, lines 48-64). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the thickness of the wall of the shaft of Fulkerson et al. in order to achieve the desired degree of flexibility of the wall in order to allow for intravascular maneuvering depending on the particular desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claims 87 and 90, since the Kevlar is embedded in a polymeric material (col. 4, lines 48-64), the Kevlar corresponds to a layer and the polymeric material forms two separate different layers (i.e. the polymeric material that surrounds [above and below the Kevlar layer] the Kevlar), and these layers have different flexibilities because they comprise different materials.

In regard to claims 88 and 91, Fulkerson et al. teach that the shaft includes a region that comprises a polyamide having a hoop stress of greater than 3500 psi because Fulkerson et al. teach that the shaft comprises Kevlar™ fiber (col. 4, lines 48-64), which has a tensile strength of up to 400 Kpsi (400,000 psi) as evidenced by Berg et al. (USPN 5,674,208, see col. 1, lines 55-

62). Since the tensile strength of Kevlar™ approaches 20 times greater than Applicant's claimed minimum tensile strength, the hoop stress (hoop strength) of Kevlar™ is also significantly greater than Applicant's claimed minimum hoop stress.

In regard to claims 130-133, Fulkerson et al. teach that the shaft may include a copolymer such as Pebax ™ (col. 4, lines 48-64: for example, the one of ordinary skill in the art would have recognized to have used Pebax ™ as the polymeric material that embeds the Kevlar™).

In regard to claims 140-143 and 150-153, Fulkerson et al. fail to explicitly teach the thickness of the wall of the shaft. However, Fulkerson et al. teach that while the wall should be strong enough to withstand the expansion force of the stent, it should also be flexible enough to allow for intravascular maneuvering (col. 4, lines 48-64). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the thickness of the wall of the shaft of Fulkerson et al. in order to achieve the desired degree of flexibility of the wall in order to allow for intravascular maneuvering depending on the particular desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claims 144-149, Fulkerson et al. teach the structural limitations that are positively recited in claims 144-149. Limitations such as "the distal inner lumen is a guide wire lumen" (claim 145) are intended use phrases that have not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987).

Response to Arguments

7. Applicant's arguments regarding the 35 U.S.C. 102 and 103 rejections made of record in the previous Office Action mailed June 9, 2008 are moot due to the withdrawal of these rejections in this Office Action due to Applicant's amendments in claims 74, 80, 84 and 89 in the Amendment filed September 11, 2008.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye, can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Walter B Aughenbaugh /
Examiner, Art Unit 1794

11/24/08